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MR# 353533

April 17, 2013

**Via Overnight Courier**

TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428
US Environmental Protection Agency
1201 Constitution Ave, NW
Washington, DC 20004-3302
Attention: TSCA Section 8(e) Coordinator



2013 APR 18 AM 11:07

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EPA/OPPT/CBIC**Draft Final Report of an *in vitro* Mammalian Cell Gene Mutation Assay at the Thymidine Kinase locus (TK^{+/+}) using NPG-THPA hemiester, CAS # 41026-17-9**

The European office of the Huntsman Advanced Materials Division (Huntsman) has received a draft final report from an *in vitro* Mammalian Cell Gene Mutation Assay at the Thymidine Kinase locus (TK^{+/+}) using 4-Cyclohexene-1,2-dicarboxylic acid, 2,2-dimethyl-1,3-propanediyl ester (also referred to as: NPG-THPA hemiester), CAS# 41026-17-9. This study was conducted using the standard OECD 476 protocol: "Genetic Toxicology: In Vitro Mammalian Cell Gene Mutation Test" and was conducted at WIL Research Europe B.V. in the Netherlands. The results of this genetic toxicity study indicate that this product is considered to be mutagenic in this cell culture system in the presence of an S-9 metabolic activation system. While the information was obtained from a draft report, the final report is not expected to be substantially different from this report with regard to the conclusions of the study.

Huntsman is submitting this information pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). Huntsman has not made a determination as to whether a significant risk of injury to human health or the environment is actually presented by these findings.

These study data can be summarized as follows:

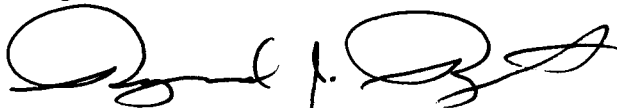
- Although elevated mutation frequencies were observed in the first experiment with S-9 metabolic activation, they occurred at test substance concentrations that produced levels of cytotoxicity outside of the laboratory's criteria for an acceptable study.
- In the second and third experiment with S-9 metabolic activation, elevated mutation frequencies were observed at test material concentrations that were within laboratory's criteria for acceptable cytotoxicity levels for this test system. These increases in mutation frequency were a 4.0 fold increase in the second experiment, and 8.9 fold in the third experiment. Both of these experiments met the laboratory's criteria for an acceptable study, and met the requirements for a positive (mutagenic) response in the presence of S-9 activation.

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- NPG-THPA hemiester was not mutagenic in this mutagenicity evaluation in the absence of S-9 metabolic activation

As always, if I can provide any additional information on the above study, please call me at (281) 719-3017, or contact me via e-mail at: Ray_Papciak@Huntsman.com.

Regards,

A handwritten signature in black ink, appearing to read 'Ray J. Papciak', with a stylized flourish at the end.

Raymond J. Papciak
Manager, Product Safety

HUNTSMAN

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MR# 353535

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OFFICE

April 17, 2013

Via Overnight Courier

TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428
US Environmental Protection Agency
1201 Constitution Ave, NW
Washington, DC 20004-3302
Attention: TSCA Section 8(e) Coordinator

Draft Final Report of an *In Vitro* Chromosome Aberration Test in Chinese Hamster Ovary (CHO-WBL) cells using NPG-THPA hemiester, CAS # 41026-17-9.

Dear Sir or Madam:

The European office of the Huntsman Advanced Materials Division (Huntsman) has received a draft final report from an *In Vitro* Chromosome Aberration Assay using 4-Cyclohexene-1,2-dicarboxylic acid, 2,2-dimethyl-1,3-propanediyl ester (also referred to as: NPG-THPA hemiester), CAS# 41026-17-9. This study was conducted using a standard OECD 473 protocol: "In Vitro Mammalian Chromosome Aberration Test" and was conducted at WIL Research Laboratories in Skokie, IL. The results of this genetic toxicity study indicate that this substance is considered to be clastogenic in this cell culture system in the presence of an S-9 metabolic activation system. No clastogenic effects were observed in the absence of an S-9 metabolic activation system. While the information was obtained from a draft report, the final report is not expected to be substantially different from this report with regard to the conclusions of the study.

Huntsman is submitting this information pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). Huntsman has not made a determination as to whether a significant risk of injury to human health or the environment is actually presented by these findings.

These study data can be summarized as follows:

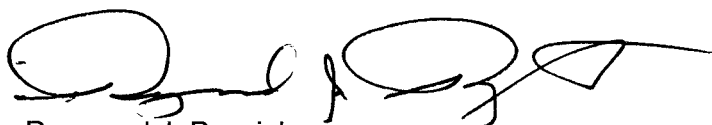
- In the presence of an S-9 metabolic activation system, NPG-THPA hemiester induced statistically significant, dose-dependent increases in the number of cells with chromosome aberrations.
- In the presence of an S-9 metabolic activation system, NPG-THPA hemiester induced a statistically significant increase in the number of cells with greater than 1 aberration per cell in the highest concentration tested (4250 mcg/mL).
- No increases in the number of cells with chromosome aberrations were observed in the absence of an S-9 metabolic activation system using NPG-THPA hemiester.

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- There were no effects on the number of polyploid cells or the number of cells with endoreduplicated chromosomes using NPG-THPA hemiester either in the presence or absence of an S-9 metabolic activation system. It can be concluded that this substance does not affect mitotic processes and cell cycle progression and does not induce numerical chromosome aberrations under the conditions of this study.
- This study met the laboratory's criteria for a positive (clastogenic) response, and also met the laboratory's criteria for an acceptable study.

As always, if I can provide any additional information on the above study, please call me at (281) 719-3017, or contact me via e-mail at: Ray_Papciak@Huntsman.com.

Regards,

A handwritten signature in black ink, appearing to read 'Ray Papciak', with a stylized flourish extending to the right.

Raymond J. Papciak
Manager, Product Safety

From: (281) 719-3028
 Maryann DeMaria
 Huntsman Corporation
 8600 Gosling Road

Origin ID: MIFA



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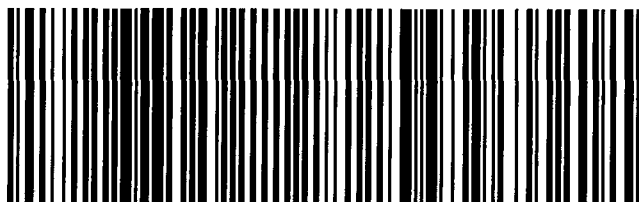
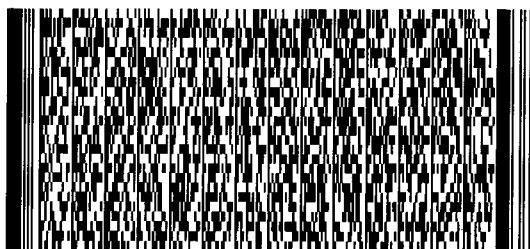
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